

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Manne Satyanarayana REDDY et al.

Art Unit: 1626

Application No.: 10/729,837

Examiner: E. O. Sackey

Filed: December 4, 2003

For: POLYMORPHIC FORMS OF ZIPRASIDONE  
AND ITS HYDROCHLORIDE SALT AND  
PROCESS FOR PREPARATION THEREOF

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Sir:

**RESPONSE**

In response to the Office Action that was mailed on May 2, 2006 for the subject application, applicants request consideration of the following discussion. As this response is not being submitted within the established period, a petition to extend the period to September 2, 2006 is also being submitted.

Claims 1-56 are pending in the application and a restriction requirement has been imposed involving the following claim groupings:

Group I - claims 1-16, 33, and 34 to amorphous ziprasidone hydrochloride, pharmaceutical compositions containing the amorphous form, and a method of treatment using the amorphous form;

Group II - claim 17 to a process for making ziprasidone hydrochloride;

Group III - claims 18-21 to a process for making amorphous ziprasidone hydrochloride;

Group IV - claims 22-32 to a process for making amorphous ziprasidone hydrochloride;

Group V - claims 35-46 and 56 to a crystalline form of ziprasidone, a composition containing the crystalline form, and a method of treatment using the crystalline form;  
and

Group VI - claims 47-55 to a process for preparing a crystalline form of ziprasidone, and a composition containing the crystalline form of claim 35.

Applicants are being required to select one of the groups, for examination.

Office policy for restricting the claims of an application has been established by M.P.E.P. § 803:

Under the statute, the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 802.01, § 806.06, and § 808.01) or distinct (MPEP § 806.05 - § 806.05(j)).

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02.

This restriction requirement does not comply with established policy, since there has been no determination that the various groups of claims can support separate patents, that is, they are patentable over each other. See M.P.E.P. § 802.01. Without this determination being made, the requirement should not be maintained.

All of the pending claims relate only to the single known chemical compound having the adopted name "ziprasidone," and to the hydrochloride salt of the compound. Contrary to the assertion in the Office Action, there is not a significant difference in the classification of the various "inventions," and this is made apparent by the statements that all of the claims are within classes 544 and 514. There also is not a large, divergent number of reagents used in the processes. No *prima facie* indication of undue burden has been set forth.

It will not be possible to examine any of the claims without conducting a search to find all of the known polymorphic forms of ziprasidone compounds and the processes for preparing them. Once that search has been performed, all of the pending claims can be examined together without any undue burden.

Since the instant requirement is not in compliance with official policies, and therefore is improper, withdrawal of the restriction requirement and examination of all pending claims is respectfully requested. However, if the requirement is to be maintained, applicants provisionally select the claims of Group I (claims 1-16, 33, and 34) for further proceedings.

Should there be any issues remaining in connection with this response, please contact the undersigned to facilitate their resolution.

Respectfully submitted,

/R. A. Franks/

Robert A. Franks  
Reg. No. 28, 605  
Attorney for Applicants

August 14, 2006

Dr. Reddy's Laboratories, Inc.  
200 Somerset Corporate Blvd., Seventh Floor  
Bridgewater, New Jersey 08807-2862  
Telephone 908-203-6504  
Facsimile 908-203-6515